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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 10/659,094   | 09/10/2003  | Cecile Combeau       | USST01010 US CNT     | 4317             |
| 5487   | 7590        | 11/29/2004           | EXAMINER             |                  |
| ROSS J. OEHLER<br>AVENTIS PHARMACEUTICALS INC.<br>ROUTE 202-206<br>MAIL CODE: D303A<br>BRIDGEWATER, NJ 08807 |             |                      | WALLER, ROBIN REGINA |                  |
|  |             |                      | ART UNIT             | PAPER NUMBER     |
|  |             |                      | 1626                 |                  |

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/659,094

**Applicant(s)**

COMBEAU ET AL.

**Examiner**

Robin R. Waller

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 6-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/04/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_

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Claims 1-15 are pending in this application

### ***Information Disclosure Statement***

Applicant's Information Disclosure Statement, filed 12/04/2003, have been considered.

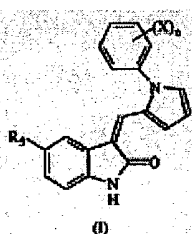
### ***Priority***

This application claims the benefit of PCT/FR02/00852 03/11/2002 filed

3/1/2002

### ***Response to Restriction***

Applicants' election of Group I, claims 1 and 5, drawn to compounds of formula (I),



, depicted in claim 1 – 5 (wherein **R 5** is selected from



the following amide group

, R2 is C1-C3alkyl and X

is a CL, CR or F and n is 1-3 ) with traverse is acknowledged. The traversal is not found

persuasive because applicant did not clearly point out the defects in the restriction

requirement. Each group is directed to art recognized divergent subject matter which require

different searching strategies for each group. Moreover, the examiner must perform a

commercial database search on the subject matter of each group in addition to a paper search,

which is quite burdensome to the examiner. In regards to the request for rejoinder, as stated

on page 7 of the restriction requirement, rejoinder will be permitted when a product claim is

found allowable and then the withdrawn process claims which depend from or otherwise

include all the limitations of an allowed product claim will be rejoined.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term isomer recited in claim 1, line 11 is indefinite. Isomers, by definition isomers are compounds having the same empirical formula and this does not mean stereoisomers alone if that is what Applicant intend to claim. It is suggested to delete the term "isomer" and replace it with terms such as stereoisomer.

***Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter

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sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5886020 Tang et al. Applicants claim the compound below:

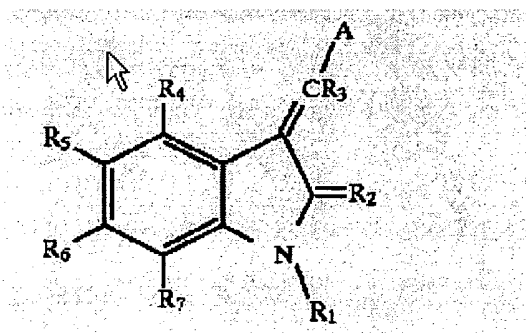


Determination of the scope and content of the prior art (MPEP §2141.01)

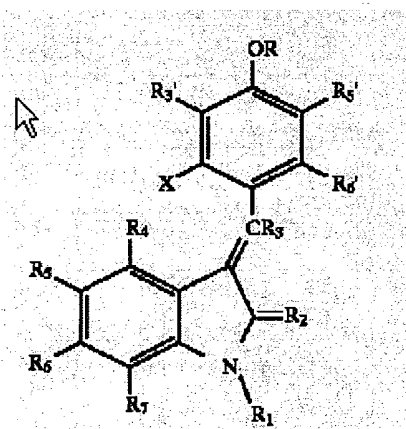
Tang et al. teach a bicyclo indoline ring of Formula 1 wherein R1 is a H, R 2 is an O, R3 is a hydrogen, R4 is an H, R5 is a H, R6 is a NHC (O)R, R7 is a H, A is a heteroaryl and

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optionally substituted at one or more positions with an aryl. This invention does not disclose a halogen substituent at the aryl ring attached to the heteroaryl group.



However, Tang et al. teach the compound of Formula III below wherein R is a H, R1 is a H, R2 is a O, R3 is a hydrogen, R4 is a H, R5 is a H, R6 is a NHC (O) R, R7 is a H, X is a halogen selected from, Br, Cl, F or I.



Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

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The difference between the prior art and the instant claims is that in the instant claims, a halogen selected from CL, Br or F is optionally substituted on the phenyl ring. The prior art does not disclose a halogen on the phenyl ring of Formula III. However, Tang et al does disclose compound with a halogen attached to the phenyl ring on Formula I.

*Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)*

Tang et al give guidance to prepare the instant Formula I in column 9 lines 1-35, and the compound of Formula III, column 10 lines 35 –65, column 11, lines 2-5 line 23, wherein R6 is an amide, and R2 is C1-C3 and X is Cl, Br or F. One of ordinary skill in the art would be motivated to use the teachings of Tang et al. to prepare instant compounds wherein the phenyl ring is optionally substituted with a halogen because the same reference teaches both compound III and I. Further, both compounds have the same method use as the instant compound, ie. regulating cell proliferative diseases such as cancer. Thus, a strong case of prima facie obviousness has been established.

***Claim Objections***

Claim 1 is objected to because of the following informalities: n is between 1 and 3 should be deleted. Examiner suggests n= 1- 3 or n=2. Appropriate correction is required.

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robin Waller whose telephone number is (571) 272-2901. Ms. Waller can normally be reached Monday through Friday 8:30AM to 6:00PM.

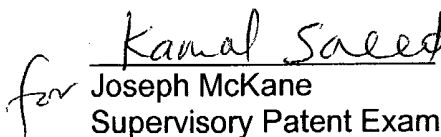
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 703-746-9879.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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